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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/621,146	07/21/2000	Chryslain Sumian	BJA 254A	3940

7590 09/24/2002

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515 Shaker Road
East Longmeadow, MA 01028

EXAMINER

DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/24/2002 11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/621,146

Applicant(s)

SUMIAN, CHRYSLAIN

Examiner

Robert M DeWitty

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, and 4-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2, 4-20 are pending in the instant application. Acknowledgement is made of Applicant's request for continued examination filed 7/25/02.

Claim Rejections - 35 USC § 112

1. Claims 1-2, and 4-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has included the limitations of the composition used "with an intact stratum corneum" and volume swelling "to prevent collapse of said follicle during release of said compound/drug". However, these limitations were not contained in the originally filed nonprovisional application (filed 7/21/00). As such, they are held to be new matter.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 2, 10, 11, 12, 14, 15, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (U.S. Pat. No. 4,292,299).

Suzuki teaches slow-releasing medical preparations that can be administered to wet mucous surface of a mucous membrane and skin of men or animals. The preparation has an adhesive layer and a non-adhesive layer; the adhesive layer has the

property of swelling upon moistening, and as it swells, slowly releasing the medicament contained in the preparation. A list of suitable polymers are contained in Table 1, col. 6.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-2, 4-5, and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al., further in view of Schaefer et al. (U.S. Pat. No. 5,292,512).

As stated, Suzuki teaches a medical preparation containing an adhesive layer and a non-adhesive layer to be administered to wet mucous of mucous surfaces and skin.

Schaefer teaches the use of microspheres containing active products for topical application. The microspheres are designed such that when the spheres enter the follicles, they diffuse the active product into the follicular canal and surrounding tissues. The microspheres can be made using polymers that swell. Schaefer teaches that the benefit of using such microspheres is the active product can be brought specifically to the target regions with no secondary effects on the skin regions surrounding the follicular channel, in comparison to topical applications which do not have desired effectiveness because the epidermis forms a barrier.

It would have been obvious to one having ordinary skill in the art to use microspheres in the medical preparation of Suzuki's because they would want to target

specific regions for treatment, as opposed to simply applying the topical application and risking secondary effects on nearby follicular channels (where treatment is not desired).

Response to Arguments

4. Applicant's arguments filed 7/25/02 have been fully considered but they are not persuasive. Applicant's asserts that the amended claim is sufficient to overcome the prior art of record. However, the amendment is considered new matter by the examiner as it was not disclosed in the original application filed. The previous rejections are thus maintained.

5. This is a request for continued examination of applicant's earlier Application No. 09621,146 aims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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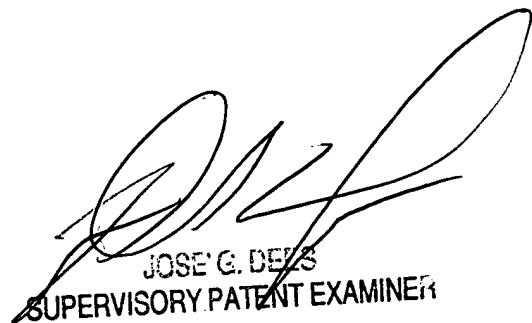
the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
September 17, 2002



JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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